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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,769	03/07/2002	M. Javad Khosravi	28758.65	9645

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,769	KHOSRAVI ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 17-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 17-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17-24, as specifically drawn to a diagnostic method comprising collecting a body fluid from an individual, measuring an insulin-like growth factor binding protein (IGFBP) concentration, measuring a tumor marker concentration, calculating an indicator ratio based upon the measured concentrations, wherein the indicator ratio provides a means for discriminating between benign disorders and cancer, and measuring an insulin-like growth factor (IGF) concentration, wherein the indicator ratio is based upon at least two of the measure concentrations, classified in class 435, subclass 4.

(Upon election of Group I, the applicant must choose ONE IGFBP from those listed in Claim 20 and ONE tumor marker from those listed in Claim 22, as each IGFBP and tumor marker is a distinct invention requiring separate searches, NOT a species)

II Claims 25-31, as specifically drawn to a diagnostic method comprising collecting a body fluid from an individual, measuring an insulin-like growth factor binding protein (IGFBP) concentration, measuring a growth factor concentration, measuring a tumor marker concentration, and calculating an indicator ratio based upon the measured concentrations, wherein the indicator ratio provides a means for discriminating between benign disorders and cancer, further comprising measureing an insulin- like growth factor (IGF)concentration, classified in class 435, subclass 4.

(Upon election of Group II, the applicant must choose ONE growth factor from those listed in Claim 26, ONE IGFBP from those listed in Claim 27, and ONE tumor marker from those listed in Claim 29, as each growth factor, IGFBP and tumor marker is a distinct invention requiring separate searches, NOT a species)

III. Claims 32-36, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a prostate specific antigen (PSA) concentration, measuring an insulin-like growth factor binding protein 3 (IGFB-3) concentration, and calculating an indicator ratio based upon the measured concentration, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

IV. Claim 37, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a prostate specific antigen (PSA) concentration, measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio of (intact IGFBP-3/total IGFBP-3)/PSA based upon the measured concentrations, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

V. Claim 38, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a prostate specific antigen (PSA) concentration, measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio of intact IGFBP-3/PSA based upon the measured concentrations, wherein the indicator ratio of

intact IGFBP-3/PSA provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

VI. Claim 39, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a prostate specific antigen (PSA) concentration, measuring an insulin-like growth factor I (IGF-I) concentration, measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio of (IGF-I/intact IGFBP-3/total IGFBP-3)/PSA based upon the measured concentrations, wherein the indicator ratio of intact IGFBP-3/PSA provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

VII. Claim 40, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a prostate specific antigen (PSA) concentration, measuring an insulin-like growth factor I (IGF-I) concentration, measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio based upon at least two measured concentrations, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

VIII. Claim 41, as specifically drawn to a diagnostic method for discriminating between benign prostate disorders and prostate cancer in an individual, comprising collecting a body fluid from the individual, measuring a kallikrein concentration, measuring an insulin-like growth factor I (IGF-I) concentration, measuring an insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio based upon at least two measured concentrations,

wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 5.

IX. Claims 42-48, as specifically drawn to a diagnostic method, comprising collecting a body fluid from the individual, measuring the tumor marker concentration of PSA, measuring a concentration selected from the group of insulin-like growth factor I (IGF-I) and insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio based upon two measured concentrations, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

X. Claims 42 and 49-54, as specifically drawn to a diagnostic method, comprising collecting a body fluid from the individual, measuring the tumor marker concentration of kallikrein, measuring a concentration selected from the group of insulin-like growth factor I (IGF-I) and insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio based upon two measured concentrations, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

XI. Claims 42 and 55, as specifically drawn to a diagnostic method, comprising collecting a body fluid from the individual, measuring the tumor marker concentration, measuring a concentration selected from the group of insulin-like growth factor I (IGF-I) and insulin-like growth factor binding protein 3 (IGFBP-3) concentration, and calculating an indicator ratio based upon two measured concentrations, wherein the indicator ratio provides a means for discriminating between benign prostate disorders and prostate cancer, classified in class 435, subclass 4.

(Upon election of Group XII, the applicant must choose ONE tumor marker from those listed in Claim 55, as each tumor marker is a distinct invention requiring separate searches, NOT a species)

The inventions are distinct, each from the other because of the following reasons:

The invention of Groups I-XI are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group I is drawn to a diagnostic method wherein an insulin-like growth factor concentration is measure, whereas Group II is drawn to a diagnostic method comprising measuring any growth factor concentration. In addition, Group III is drawn to a diagnostic method comprised of calculating an indicator ratio based upon the measured concentrations, whereas Group IV is drawn to a diagnostic method comprising calculating an indicator ratio of (intact IGFBP-3/total IGFBP-3)/PSA based upon the measured concentration. Furthermore, Group X is drawn to a diagnostic method using PSA as a tumor marker, whereas Group XI is drawn to a diagnostic method using kallikrein as the tumor marker.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

Primary Examiner / 1642